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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,054	08/21/2006	Jacob Westman	WESTMAN 3	5605
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW			EXAMINER	
			RAHMANI, NILOOFAR	
SUITE 300 WASHINGTON, DC 20001-5303			ART UNIT	PAPER NUMBER
			1625	
			MAIL DATE	DELIVERY MODE
			04/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Application No. Applicant(s) 10/590,054 WESTMAN ET AL. Office Action Summary Examiner Art Unit NILOOFAR RAHMANI 1625 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on remark dated on 12/23/2008. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-7.9-12 and 14-20 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) 18 is/are allowed. 6) Claim(s) 1-3 and 11-12 and 14-17 is/are rejected. 7) Claim(s) 4-7,9,10,19 and 20 is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 02/09/2009.

Attachment(s)

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

1. Claims 1-7, 9-12, 14-20 are pending and claims 8 and 13 are cancelled in the instant application.

- The rejection of claim 4 for "preparing" under 112, second paragraph is withdrawn in view of applicant's argument and amendment in paper dated on 12/23/2008.
- The rejection of claims 1-14 for "prodrug" under 112, second paragraph is withdrawn in view of applicant's argument and amendment in paper dated on 12/23/2008.
- 4. The rejection of claims 1-2 and 11-12 and 14-17 under 112, first paragraph is maintained for reason of record. Applicants argue that there is a declaration in lieu of affidavit under 37 CFR 1.132 by DR. Nina Mohell, a non-inventor, but a person involved in and closely familiar with the present invention. It is examiner's position that the declaration under 37 CFR 1.132 is acceptable but the claim language need to be change to "a method of treating a disorder by using of formula (I)".

# 5. New Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim

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contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 3 has a new proviso, wherein at least on of R1 and R2 is

$$R^3$$
 is =0,--8-or -NR<sup>5</sup>; provided that at least one of  $R^4$  and  $R^2$  is selected from -CH<sub>2</sub>-O-CO-R<sup>5</sup>, -CH<sub>2</sub>-O-CO-NR<sup>4</sup>R<sup>5</sup> and -CH<sub>2</sub>-O-CO-OR<sup>5</sup>;

The only description of R1 and R2 is that they are from a large group of things. Not just those three items. This spec shows this smaller grouping but only for the preparation of the final compounds.

This is a NEW MATTER rejection. Removal of all new matter is required, In re Russmussen 210 USPQ 325.

If the New matter rejection will be withdrawn, then the rejection under 35 U.S.C. 102(b) over Bykov et al. and Nielsen et al. and Singh et al. and Shimizu et al. and Elkin et al. and Dickinson et al. will be maintained

### 6. Claim Objections

Claims 4-7, 9-10, 19 and 20 are objected to as being dependent upon a cancelled base claim 3, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

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#### 7. Allowable Subject Matter

Claim 18 is patentable over Nielsen et al., journal of organic chemistry 919660, 3194), pages 1053-9, which includes the exemplified compound:

> RN 5291-13-4 CN 3-Quinuclidinone, 2-(ethoxymethyl)-

, which has a CH2-OEt substituted quinuclidinone ring at the R1 and R2 position. At the position corresponding to CH2-OEt, the instant application requires that this position must be different than CH2-OEt. Therefore, the claims are free of prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first

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reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

 Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/NILOOFAR RAHMANI/

04/14/2009

/D. Margaret Seaman/

Primary Examiner, Art Unit 1625

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